

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS
CORPORATION,

Plaintiff,

V.

LIQUIDIA TECHNOLOGIES, INC.,

Defendant.

C.A. No. 23-975 (RGA) (SRF)

REDACTED - PUBLIC VERSION

Original filing date: October 8, 2024

Redacted filing date: October 21, 2024

PLAINTIFF UNITED THERAPEUTICS CORPORATION'S FIRST NOTICE OF DEPOSITION UNDER FED. R. CIV. P. 30(b)(6) TO DEFENDANT

PLEASE TAKE NOTICE that pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure, Plaintiff United Therapeutics Corporation (“UTC”), by and through its attorneys, will take the deposition upon oral examination of Defendant Liquidia Technologies, Inc. (“Liquidia”) by or through one or more of Defendant’s officers, directors, managing agents, or other persons who consent to testify on Defendant’s behalf with respect to the matters set forth in Schedule A attached hereto.

The deposition will commence on a mutually agreed-upon date at the offices of Goodwin Procter LLP, 620 Eighth Avenue, New York, NY 10018, or at such other place and time as may be agreed upon by the parties. The deposition shall continue from day to day until completed. The deposition will be taken before a court reporter, notary public, or other officer authorized by law to administer oaths and will be recorded by stenographic, audio, audiovisual, video, real-time computer means, and/or remote-deposition means.

Separately for each numbered topic of examination in the attached Schedule A, Defendant shall identify to Plaintiff in writing, no later than two (2) weeks before the date of the deposition: (a) the name and employment position of each designee who has consented to testify on Defendant's behalf in response to this Notice; and (b) all matters set forth below as to which each such designee has agreed to testify on behalf of Defendant. If more than one person is required to testify on any individual topic set forth in Schedule A, different individuals shall be provided for each part of that topic. In accordance with Rule 30(b)(6) of the Federal Rules of Civil Procedure, Plaintiff remains available to meet and confer with Defendant regarding the matters for examination.

Pursuant to Rules 30(b)(2) and 34 of the Federal Rules of Civil Procedure, Defendant is hereby requested to produce, at least two (2) weeks before the deposition, any and all documents and things in its possession, custody, or control that in any way refer to or concern any of the topics set forth in the attached Schedule A that have not previously been produced to Plaintiff in this action. Plaintiff reserves the right to continue or postpone the deposition should Defendant fail to timely produce such documents and things before the deposition.

Plaintiff serves this Notice without waiver of any objections to the deficiencies in Defendant's document production and other discovery responses concerning the subject matter described in Schedule A and reserves the right to continue this deposition as necessary in light of any subsequent document production and other discovery responses by Defendant.

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/s/ Michael J. Flynn

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October 8, 2024

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SCHEDULE A

DEFINITIONS

1. UTC hereby incorporates by reference the Definitions found in UTC's First Set of Interrogatories (No. 1), served on May 6, 2024, UTC's First Set of Requests for the Production of Documents and Things (Nos. 1-17), served on May 28, 2024, UTC's Second Set of Requests for the Production of Documents and Things (Nos. 18-85), served on July 24, 2024, and UTC's Second Set of Interrogatories (Nos. 2-9), served on August 6, 2024.

INSTRUCTIONS

1. In responding to these 30(b)(6) topics, You are required to furnish all information that is available to You or subject to Your reasonable inquiry, including information in the possession of Your officers, directors, employees, attorneys, accountants, advisors, agents, or other persons directly or indirectly employed by, or connected with, You or Your attorneys, and any person otherwise subject to Your control.

2. If You object to all or any part of a topic, state the grounds of the objection with sufficient specificity to permit determination of the basis for, and propriety of, such objection, including citations where legal authority is relied upon, and provide a witness to testify about the topic to the extent the topic is not objectionable. All objections shall be signed by the attorney making them.

3. If any information called for by the topic is unknown to You, please provide a witness to testify about the topic to the full extent of Your knowledge.

4. If You are unable to understand any of the following topics, or any of the applicable Definitions or Instructions, Plaintiff requests that You immediately seek clarification through Plaintiff's counsel.

5. Definitions or uses of words or phrases in this Notice are not intended to be, and shall not be, construed as admissions as to the meaning of words or phrases at issue in this action, and shall have no binding effect on Plaintiff in this or any other proceeding.

TOPICS OF EXAMINATION

TOPIC NO. 1:

Liquidia's research and development activities related to the development of treatment regimens to improve exercise capacity in patients with PH-ILD, including any Liquidia NDA Product.

TOPIC NO. 2:

Research and development activities performed by or on behalf of Liquidia regarding the administration of Yutrepia to patients having PH-ILD including all relevant pre-clinical or clinical studies or trials.

TOPIC NO. 3:

Liquidia's communications, collaborations, contracts, and consultations with consultants, experts, clinicians or other third parties regarding the research and development of Yutrepia for PH-ILD.

TOPIC NO. 4:

The mechanism of action by which inhaled treprostinil (including Yutrepia) improves exercise capacity, improves forced vital capacity, increases six-minute walk distance, reduces plasma concentration of NT-proBNP, reduces exacerbations of interstitial lung disease, and/or reduces clinical worsening events in patients with PH-ILD.

TOPIC NO. 5:

Whether Liquidia contends that Yutrepia is safe and effective for PH-ILD patients, and if so why, including whether and why Liquidia concluded that Yutrepia is safe and effective for PH-

ILD patients prior to conducting, sponsoring, or funding phase 3 trials or studies designed to assess Yutrepia's safety and efficacy in patients with PH-ILD.

TOPIC NO. 6:

Liquidia's knowledge regarding any comparative studies relating the safety and efficacy of TYVASO®, TYVASO DPI®, or any Treprostinil Product to Yutrepia.

TOPIC NO. 7:

The bases for Liquidia's decision to represent to the FDA that Yutrepia is safe and effective for PH-ILD patients in Liquidia's NDA Amendment. *See e.g.*, LIQ_PH-ILD_00091022.

TOPIC NO. 8:

How Yutrepia compares to or differs from Tyvaso®, Tyvaso DPI®, or any Treprostinil Product including with respect to patient population, target market, delivery device, dosage, efficacy, safety, and product quality..

TOPIC NO. 9:

Liquidia's regulatory submissions for Yutrepia including: (1) Liquidia's NDA, Liquidia's NDA Amendment, and any subsequent amendments or supplemental NDAs for Yutrepia; (2) All correspondence with FDA relating to Liquidia's NDA and Liquidia's NDA Amendment, and any subsequent amendments or supplemental NDAs for Yutrepia; (3) Liquidia's current regulatory tracking logs, including Liquidia's IND Sequence Tracker, Liquidia's NDA Sequence Tracker, and Liquidia's NDA Regulatory Chronology log; (4) Any IND submitted by or on behalf of Liquidia to FDA concerning the administration of treprostinil to PH-ILD patients; and (5) Any DMF submitted to FDA in connection with or referenced by Liquidia's NDA.

TOPIC NO. 10:

Liquidia's first awareness of the Asserted Patent.

TOPIC NO. 11:

Any consideration or decision by Liquidia regarding whether or not to modify the proposed package insert or labeling of any Liquidia NDA Product including any analysis, evaluation, investigation, or discussion concerning those considerations and decisions, such as Liquidia's consideration and decision to (or not to) incorporate portions of the INCREASE or ASCENT study results.

TOPIC NO. 12:

The factual basis for Roger Jeffs's January 8, 2024 statement that UTC "assert[s] a new patent that was procured without submitting highly material prior art references and important additional information to the USPTO." See January 8, 2024 Publication, Liquidia Corporation Files Response to United Therapeutics Lawsuit and Files Counterclaims.

TOPIC NO. 13:

The factual basis for Roger Jeffs's May 14, 2024 statements regarding the existence of "encouraging initial data from our ASCENT trial of YUTREPIA in PH-ILD," as well as that "the expanded PH-ILD market . . . is only marginally penetrated at this time" See May 14, 2024 Liquidia Corporation Q1 2024 Earnings Call Transcript, <https://seekingalpha.com/article/4693098-liquidia-corporation-lqda-q1-2024-earnings-call-transcript>.

TOPIC NO. 14:

The factual basis for Roger Jeffs's March 17, 2022 statement that "the value of a dry powder formulation like YUTREPIA is that the portability of the product will greatly transition [the WHO Group 1 PAH] market and rapidly from nebulized for formulations to dry powder formulations." See March 17, 2022 Liquidia Corporation Q4 2021 Earnings Call Transcript,

<https://seekingalpha.com/article/4496179-liquidia-corporations-lqda-ceo-roger-jeffs-on-q4-2021-results-earnings-call-transcript>.

TOPIC NO. 15:

All “top-to-top conversations with leadership of the payers” (*see* January 10, 2024 J.P. Morgan 42nd Annual Healthcare Conference Transcript (UTC_PH-ILD_005067; ECF No. 34, Ex. 3 at 11)), and Liquidia’s “position[ing of] YUTREPIA as a preferred product,” (*see* May 4, 2023 Liquidia Corporation Q1 2023 Earnings Call (UTC_PH-ILD_005040)).

TOPIC NO. 16:

The factual basis for Rusty Schundler’s January, 10, 2024 statement that “the other thing to keep in mind is the '327 patent, what that's really covering is physicians treating PH-ILD patients with TYVASO in accordance with the TYVASO label. And doctors have been doing that for more than 10 years. Rajeev Sagar, our CMO, when he was treating patients, he was treating patients with TYVASO, PH-ILD patients with TYVASO. And so again, we don't think there's anything in that patent that's anything new, and certainly not new as of 2020,” (*see* January, 10, 2024 Transcript of Liquidia’s presentation at the 2024 JPMorgan Healthcare Conference, UTC_PH-ILD_005067 at -065).

TOPIC NO. 17:

Any communications between Liquidia and key opinion leaders (“KOLs”) and/or Scientific Advisory Board members between 2009 and 2024 related to the use of any Treprostinil Product for the treatment of PH-ILD.

TOPIC NO. 18:

Any Communications by Liquidia to past, current, or potential investors, of Liquidia referring directly or indirectly to the Asserted Patent, any Liquidia NDA Product, or any Treprostinil Product for use with PH-ILD.

TOPIC NO. 19:

Any licenses or settlement agreements related to Yutrepia or any Treprostinil Product.

TOPIC NO. 20:

Any analyses, considerations or evaluations of the market and sales, or potential market and sales, of Yutrepia or any Treprostinil Product.

TOPIC NO. 21:

Liquidia's sales and marketing strategies regarding how it targets patients.

TOPIC NO. 22:

Liquidia's past, present, and future plans and efforts to market, advertise, and promote administration of Yutrepia for PH-ILD to prescribers, health care professionals, hospitals, or any health care provider.

TOPIC NO. 23:

Liquidia's efforts to educate prescribers or health care professionals about Yutrepia for PH-ILD.

TOPIC NO. 24:

Liquidia's efforts to grow the market for Treprostinil products, including any efforts to identify new patients.

TOPIC NO. 25:

Liquidia's strategy for switching patients on other Treprostinil Products to Yutrepia.

TOPIC NO. 26:

Liquidia's plans and/or preparations to launch Yutrepia.

TOPIC NO. 27:

The date or time frame when Liquidia expects to launch Yutrepia for PAH.

TOPIC NO. 28:

The date or time frame when Liquidia expects to launch Yutrepia for PH-ILD.

TOPIC NO. 29:

How Liquidia plans to distribute Yutrepia.

TOPIC NO. 30:

Liquidia's communications with third parties regarding manufacturing, pre-commercial manufacturing, commercial manufacturing, or launch of any Liquidia NDA Product for administration to PH-ILD patients.

TOPIC NO. 31:

Any communications between Liquidia and payors, including without limitation health care plans, managed care plans, pharmacy benefit managers, hospitals, and/or government agencies, regarding formulary status, formulary coverage or placement, utilization management, pricing, and rebates or discounts for Yutrepia or any Treprostinil Product.

TOPIC NO. 32:

Any communications with wholesalers, distributors, pharmacies, retailers and other potential purchasers regarding Yutrepia.

TOPIC NO. 33:

Liquidia's manufacturing capacity for Yutrepia.

TOPIC NO. 34:

Liquidia's inventory of Yutrepia on a month-by-month basis through the present day, the purpose of such inventory, and how said inventory was used or prepared for use.

TOPIC NO. 35:

Pricing for Yutrepia (including WAC and net) as well as any rebates, discounts, or rebate programs.

TOPIC NO. 36:

Liquidia's financial documents, including forecasts and actuals, of sales, costs and market share.

TOPIC NO. 37:

The revenues and profits associated with Yutrepia.

TOPIC NO. 38:

The costs associated with Yutrepia, including cost of goods sold, marketing costs, research and development costs, clinical trial costs, SG&A costs, and any and all cost-related line items on Liquidia's most-detailed internal and public financial statements.

CERTIFICATE OF SERVICE

I hereby certify that on October 8, 2024, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on October 8, 2024, upon the following in the manner indicated:

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